K100037

SEP 23 2010

510(k) Summary

Advanced Vertebral Solutions, EXPRESS IBFD

Submitter:	ADVANCED VERTEBRAL SOLUTIONS, LLC 124 S. Maple Street Ambler, PA 19002
Contact Person	Mike Dugery President Phone: 215 534 2481 Email: mdugery@vasculabtech.com
Date Prepared	September 21, 2010
Device Class	Class II
Trade Name	Advanced Vertebral Solutions, EXPRESS IBFD
Classification Name and Number	Intervertebral Fusion Device With Bone Graft, Lumbar 21 CFR 888.3080
Classification Panel:	Orthopedics
Product Code	MAX
Predicate Devices	Paramount™ Intervertebral Body Fusion Device (K072120) and Patriot ™ Intervertebral Body Fusion Device (K072970)
Device Description	Advanced Vertebral Solutions Express IBFD AVS Express is a device for interbody fusion of the anterior column of the spine. These cages are hollow so that bone can grow through the device, fusing the adjacent bony surfaces. Advanced Vertebral Solutions Express IBFD AVS Express is a hollow device with texture on two opposing convex sides, and is offered in various lengths, widths, heights and shapes. Advanced Vertebral Solutions designed the Advanced Vertebral Solutions Express IBFD AVS Express to be placed through a transforaminal approach and to address vertebrae in the lumbosacral region of the spine.

Intended Use	The Advanced Vertebral Solutions IBF device, when used with autologous bone graft, is indicated for use in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Advanced Vertebral Solutions IBF device is to be implanted via a transforaminal approach. The device is to be used singly in the lumbosacral spine with supplemental posterior fixation.
Materials:	The implant is manufactured from ASTM2026 implant grade Polyetheretherketone (PEEK) and ASTM F136 implant grade Titanium Alloy 6Al4V.

Statement of Technological Comparison	The purpose of this submission is to obtain market clearance for the proposed the Advanced Vertebral Solutions EXPRESS IBFD. The Advanced Vertebral Solutions EXPRESS IBFD and its predicate devices have the same indications for use, have a similar design, and are made of the similar materials and chemical composition.

Summary of Technological Comparison

Characteristic	**Advanced Vertebral Solutions**	**Globus Patriot**	**IST Paramount**
Material	PEEK ZA 500 or Ti alloy	PEEK-OPTIMA®	PEEK-OPTIMA®
Radiopaque Markers	Tantalum or Ti alloy	Tantalum	Tantalum
Shape	Five Banana shapes	Banana	Banana
Surgical Approach	TLIF	Direct Posterior or TLIF	Direct Posterior or TLIF
Adjunctive Fixation	Required	Required	Optional
Bone to Implant Surface	Ridged	Ridged	Ridged
How Supplied	Non-Sterile	Non-Sterile	Non-Sterile

Nonclinical Test Summary	The following tests were performed to demonstrate that the Advanced Vertebral Solutions EXPRESS IBFD is substantially equivalent to other predicate devices. • Static and Dynamic Compression Test per ASTM F2077 • Static and Dynamic Compression Shear ASTM F2077 • Subsidence Test per ASTM F2267 • Wear Debris ASTM F2077 and ASTM F1877 • Static Expulsion Test The results of these studies showed that the subject Advanced Vertebral Solutions EXPRESS IBFD met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.
Conclusion	The Advanced Vertebral Solutions EXPRESS IBFD is substantially equivalent to its predicate devices. This conclusion is based upon the fact that this device is substantially equivalent in terms of indications for use, technological characteristics, materials, design and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Vertebral Solutions, LLC
% Mr. Mike Dugery
President
124 South Maple Street
Ambler, Pennsylvania 19002

SEP 23 2010

Re: K100037
Trade/Device Name: Advanced Vertebral Solutions EXPRESS IBFD
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 02, 2010
Received: September 03, 2010

Dear Mr. Dugery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K100637

SEP 23 2010

510(k) Number: K100037

Device Name: **Advanced Vertebral Solutions EXPRESS IBFD**

Indications:

The Advanced Vertebral Solutions EXPRESS IBFD, when used with autologous bone graft, is indicated for use in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The Advanced Vertebral Solutions EXPRESS IBFD is to be implanted via a transforaminal approach. The device is to be used singly in the lumbosacral spine with supplemental posterior fixation.

Prescription Use X **AND/OR** **Over-the-counter**

(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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